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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,599	10/03/2000	Leigh T Canham	124-796	1219

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,599

Applicant(s)

CANHAM ET AL.

Examiner

Carlos A. Azpuru

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 167-176 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 167-176 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Receipt is acknowledged of the amendment filed 1/06/2006.

The rejection of claims 167-176 under 35 USC 112, first paragraph for written description is hereby maintained.

The remainder of the rejections (35 USC 112, second paragraph and 35 USC 103(a)) are withdrawn in view of the amended claims.

Response to Arguments

Applicant's arguments filed 01/06/2006 have been fully considered but they are not persuasive.

Applicant argues that there is support in the specification for this term. However, review of the cited sections again finds no support in the specification. Applicant further attempts to prove that the particles are hydrophobic by submitting a journal article. However, for such a submission to be considered, the article should have been discussed in the background art, and provided in a PTOL-1449. Applicant is invited show specific citations (or suggestions thereof) of the term "hydrophobic" in the original specification. The inclusion of the term "hydrophobic" is considered new matter. Correction is requested.

The following rejections are cited in view of applicant's amended claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 170, 171, 173-176 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 170 and 171 also have no support in the original specification in that there is no support for the claimed ranges. Specifically, porosity ranges "between 2% and 80%", and "between 4% and 55%" are never recited (see page 3, lines 15-19). Applicant has taken intermediate values in the values set out for porosity and added ranges between them. It should also be pointed out that 80% is also not disclosed as the upper limit since higher values appear to be contemplated.

Claim 173 sets out an erosion time of “between one month and two years”. This limitation has no support in the original specification.

The specification sets out a porous implant at page 5, lines 17 and 18 which include dimensions of 4 and 20 mms. Clearly, this is larger than the 2 mm set out as the high end of the range in claims 174. No support is found in the specification for this limitation.

The specification also lacks support for a drug being distributed “ through substantially the whole volume of the material of the implant” as set out in claim 175. It is further questioned how this would be accomplished since the drug is found in the pores of the implant. Some structural silicone is necessary for the implant to have pores, and would not include the incorporated drug. It would appear this would only be accomplished by having a completely hollow silicon implant. However, this type of implant could not be described as “porous”. Clarification is requested.

The specification lacks support for an implant which is “substantially entirely resorbable mesoporous silicon”. As set out in the specification at page 4, lines 25-28; page 5, lines 1-6, the amount of porosity determines the extent of the resorption, with higher numbers corresponding to the higher amounts of resorbable material. As such, only porosity value above a certain value would qualify for fully resorbable implants.

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Macroporous implants would most likely meet this characteristic, but there is no disclosure of a value at which full resorption occurs. As such, claim 176 has no support in the original specification. Correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 168 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 168 recites the limitation "a macroporous silicon" in claim 167 which sets out a "mesoporous silicon". The pore sizes set out in claim 167 also do not correspond to that of a macroporous particle. There is insufficient antecedent basis for this limitation in the claim. Correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 167-173, 175 and 176 are rejected under 35 U.S.C. 102(b) as being anticipated by WO'97/06101 (WO'101).

WO'101 discloses a silicone particle which exist in microporous, mesoporous and macroporous form. The porosity is set out at page 3, lines 12-13 as greater than 4% and less than 70%, which clearly anticipates the claimed porosity ranges. Tissue compatibility although not taught is an inherent characteristic of the material selected. In this case, the same mesoporous silicon particles with the same porosity are selected, so that this characteristic may be considered a new characteristic of a known material. The amount of drug distributed through the implant as well as the amount of resorption are dependent upon the material and its porosity. Since the reference discloses both, both of these parameters are inherent to the material selected. The instant claims are anticipated by WO'101.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Carlos A. Azpuru
Primary Examiner
Art Unit 1615